



NOV - 6 2007

Stephen B. Davis
Patent Department
Bristol-Myers Squibb Company
P.O. Box 4000
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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,206,244

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,206,244, claims of which cover the human drug product BARACLUDE® (entecavir), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,587 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,587 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of February 23, 2007 (72 Fed. Reg. 8181). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2811 - 0) + 182 \\ &= 1,587 \text{ days (4.3 years)}\end{aligned}$$

Since the regulatory review period began January 19, 1997, after the patent issued (April 27, 1993), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

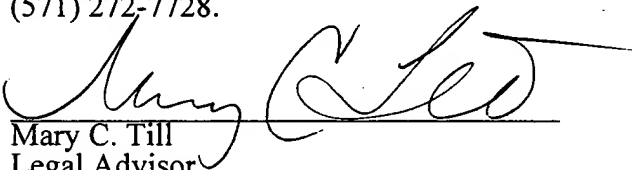
U.S. Patent No.:	5,206,244
Granted:	April 27, 1993

Original Expiration Date¹: October 18, 2010
Applicant: Robert Zahler and William A. Slusarchyk
Owner of Record: Bristol-Myers Squibb Company
Title: Hydroxymethyl (Methylenecyclopentyl) Purines and Pyrimidines
Product Trade Name: BARACLUDE® (entecavir)
Term Extended: 1,587 days
Expiration Date of Extension: February 21, 2015

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE By FAX: (571) 273-7728
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to Raul Tamayo at (571) 272-7728.



Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

RE: BARACLUDE® (entecavir)
FDA Docket No.: 2006E-0356

Attention: Beverly Friedman

¹Subject to the provisions of 35 U.S.C. § 41(b).